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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,129	08/20/2003	William A. Cook	PA-5337-RFB	5324

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COOK GROUP PATENT OFFICE
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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,129

Applicant(s)

COOK ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 11, 16, 17, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 12-15 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and comments dated 5/3/05 have been received in application serial number 10/644,129. All comments have been taken into consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 5-7, 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. 5,824,037. Fogarty et al. discloses in the invention as claimed noting figures 1 and 3-3d comprising claim 1: a graft portion (60) including a first end, a second end and a main body (64) portion generally tubular in shape that comprises a first layer of material (18); a cuff portion (62, 66), having a first edge and a second edge, located about the first end of the graft portion, the cuff portion comprising a second layer of material closely adjacent the main body portion (i.e. "87" or see col. 18, lines 58-61 "folded over"; see col. 9 lines 45-67 and col. 18, lines 58-67); and a supporting structure attached about the first end of the graft portion (the support structure is the frame and ring frames 12, 14); claim 5: wherein the supporting structure

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includes an anchoring stent attached to the cuff portion and the main body portion (see figures 3a-3d); claim 6: wherein the cuff portion comprises one or more element separate of the main body portion that are attached thereto (83); claim 7: wherein the cuff portion comprises an external sealing zone extending laterally from the main body portion, the external sealing zone configured to engage the walls of the vessel to facilitate sealing there between and reduce leakage of fluid; claim 10: wherein the cuff portion comprises a second material different than that of the main body (see col. 19 which states that the cuff liner can be fuzzy which is different than the main body of ring frames).

4. Fogarty further discloses in col 18, lines 46-67 (figure 15) that the cuffed prosthesis comprises a liner material which can be folded over. This equates to the newly added limitation in claim 11 of of "...a cuff with a second layer of material...".

5. Claims 16-17 rejected under 35 U.S.C. 102(e) as being anticipated by Chobotov 6,395,019. Chobotov discloses the invention as claimed comprising: a graft portion (10) including a main body portion; an outer cuff portion (16, having a first edge and a second edge, that is located about the first end of the graft portion and attached thereto; and an anchoring stent (24) attached to the main body portion and outer cuff portion, the anchoring stent extending proximally therefrom (see figure 1-2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. '037 in view of Lenker et al. '158. Fogarty et al. has been disclosed above however Fogarty does not specify that the outer cuff portion is folded over the main body portion. Lenker teaches that a stent graft may be provided with a cuff that is folded over the main body portion see figure 11b and col. 15, lines 5-15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to fold the cuff over the main body portion of the graft because both Fogarty et al. and Lenker teach that the graft material may extend beyond the main body and by folding over the material one could provide a better wider seal for the proximal region of the prosthesis.

Allowable Subject Matter

8. Claims 8-9, 12-15 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims

Response to Arguments

9. Applicant's arguments filed 5/3/05 have been fully considered but they are not persuasive. Applicant has amended claims 1 and 11. With regards to claim 1 applicant contends that: "*The main body portion (tapered prosthetic module 64 of the Fogarty reference overlaps with the distal end of the proximal cuff portion such that the first or leading edge of the main body portion is well proximal to the first or leading end of the proximal cuff portion and not located thereabout ...*". It is the examiners opinion that Fogarty does disclose the invention as claimed. The cuff portions (62, 66) of Fogarty do have a first and second edges. The first edge is located about the first end of the main body. The term "about" is broad and does not exclude the locations of being internally about or externally about". It does not matter whether applicant believes that the cuff extends proximally because this is not a current claim limitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Suzette J-J Gherbi
30 March 2006